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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/596,101	06/16/2000	Patrick de Baetsclier	4432US	2709

7590 04/09/2002
Allen C Turner
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P O Box 2550
Salt Lake City, UT 84110

EXAMINER

FORD, VANESSA L

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 04/09/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant's Name

09/596,101

Applicant(s)

DE BAETSELIER ET AL.

Examiner

Vanessa L. Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 4-10, 12, 14-15 and 18-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 11, 13, 16 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

FINAL ACTION

1. This Office Action is responsive to Applicant's response in paper No. 14 to the first Office Action in paper No. 11.
2. In view of Applicant's amendment and the Applicant's submission^{of} the foreign priority document, the objection to foreign priority is withdrawn.
3. In view of Applicant's amendment, the objections to the specification are withdrawn.
4. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.
5. In view of Applicant's amendment the following rejections are withdrawn.
 - a) Rejection of claims 1-3, 11, 13 and 16-17 under 35 U. S.C. 112, first paragraph.
 - b) Rejections of claims 1-5 under 35 U. S.C. 112, second paragraph.
 - c) Rejection of claims 1-2 under 35 U.S.C. 102(a).
 - d) Rejection of claims 11 and 16-17 under 35 U.S.C. 102(a).
6. The rejection of claims 1-3 and 13 under 35 U.S.C. 102(b) as anticipated by Bilej et al (*European Cytokine Network, March-April 1994*) is maintained for the reasons set forth in paper 11, page 12 of the previous Office Action.

The rejection was on the grounds that Bilej et al teach a coelomic fluid from the *Eisenia foetida* earthworm that exerts a strong trypanolytic activity. Bilej et al teach that the coelomic fluid of the earthworm contains strong proteolytic, hemolytic, bacteriolytic

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and cytolytic factors and may be an ancestral form of TNF- α . It would be inherent that the CCF-1 protein as taught by Bilej et al would comprise at least 9 contiguous amino acids of SEQ ID No: 1 or comprise the amino acid sequence of SEQ ID NO: 3 or a functional fragment thereof.

Since the Office does not have the facilities for examining and comparing applicant's polypeptide with the polypeptide of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the polypeptide of the prior art does not possess the same material structural and functional characteristics of the claimed polypeptide). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that the teaching of Bilej et al would be considered non-enabling because a person skilled in the art would not be able to predict the exact amino acid sequence (for example, SEQ ID No: 1 having trypanolytic) as used in the claimed invention.

Applicant's arguments filed January 23, 2002 in paper No. 14 have been fully considered but they are not persuasive. It is the Examiner's position that there is nothing on the record to show why the coelomic fluid from *Eisenia foetida* earthworm of the prior reference is not the same as the claimed peptide from *Eisenia foetida* earthworm. Applicant has provided no side-by-side comparison to show that the peptide (i.e. coelomic fluid with trypanolytic activity) of the prior art is not the same as the claimed peptide.

7. The rejection of claims 11 and 16-17 under 35 U.S.C. 102(b) as anticipated by Bilej et al (*Immunology Letters*, 45, 1995) is maintained for the reasons set forth in paper 11, page 12 of the previous Office Action.

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The rejection was on the grounds that Bilej et al teach a concentrated coelomic fluid composition for intra-foot pad immunization of Balb/c mice (see page 124). The composition of Bilej et al is the same as the claimed invention. It would be inherent that the concentrated coelomic fluid sample would contain a peptide comprising at least 9 contiguous amino acids of SEQ ID NO: 1 or a peptide comprising the amino acid sequence of SEQ ID NO: 3 or a fragment/epitope of either thereof.

Since the Office does not have the facilities for examining and comparing applicant's pharmaceutical composition with the pharmaceutical composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the pharmaceutical composition of the prior art does not possess the same material structural and functional characteristics of the claimed pharmaceutical composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that the teaching of Bilej et al would be considered non-enabling because a person skilled in the art would not be able to predict the exact amino acid sequence contained in the claimed pharmaceutical composition.

Applicant's arguments filed January 23, 2002 in paper No. 14 have been fully considered but they are not persuasive. It is the Examiner's position that there is nothing on the record to show why the pharmaceutical composition containing coelomic fluid from *Eisenia foetida* earthworm of the prior reference is not the same as the claimed pharmaceutical composition. Applicant has provided no side-by-side comparison to show: that the pharmaceutical composition containing (i.e. coelomic fluid from *Eisenia foetida* earthworm) of the prior art is not the same as the claimed pharmaceutical composition.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

9. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.


Vanessa L. Ford
Biotechnology Patent Examiner
April 5, 2002


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SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600